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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 211019-0212]

RIN 0694-AI41

Request for Comments Concerning the Imposition of Export Controls on Certain Brain-Computer Interface (BCI) Emerging Technology

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: The Bureau of Industry and Security (BIS) maintains controls on the export, reexport and transfer (in-country) of dual-use items and less sensitive military items pursuant to the Export Administration Regulations, including the Commerce Control List (CCL). Certain items that could be of potential concern for export control purposes are not yet listed on the CCL or controlled multilaterally, because they are emerging technologies. Among these items is Brain-Computer Interface (BCI) technology, which includes, *inter alia*, neural-controlled interfaces, mind-machine interfaces, direct neural interfaces, and brain-machine interfaces. BIS is seeking public comments on the potential uses of this technology, particularly with respect to

its impact on U.S. national security (e.g., whether such technology could provide the United States, or any of its adversaries, with a qualitative military or intelligence advantage). This document also requests public comments on how to ensure that the scope of any controls that may be imposed on this technology would be effective (in terms of protecting U.S. national security interests) and appropriate (with respect to minimizing their potential impact on legitimate commercial or scientific applications).

DATES: Comments must be received by BIS no later than [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by regulations.gov docket number BIS-2021-0032 or by RIN 0694-AI41, through any of the following:

- Federal eRulemaking Portal: https://www.regulations.gov. You can find this advance notice of proposed rulemaking by searching for its regulations.gov docket number, which is BIS-2021-0032.
- *E-mail*: PublicComments@bis.doc.gov. Include RIN 0694-AI41 in the subject line of the message.

All filers using the portal or e-mail should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC." Any page

containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL" on the top of that page. The corresponding non-confidential version of those comments must be clearly marked "PUBLIC." The file name of the non-confidential version should begin with the character "P." The "BC" and "P" should be followed by the name of the person or entity submitting the comments or rebuttal comments. Any submissions with file names that do not begin with a "P" or "BC" will be assumed to be public and will be made publicly available through https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: For questions on Brain-Computer Interface technology, contact Dr. Betty Lee, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482-5817, E-mail: Betty.Lee@bis.doc.gov. For questions on the submission of comments, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482-6057, E-mail: RPD2@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

As part of the National Defense Authorization Act (NDAA) for Fiscal Year 2019, Public Law 115-232, Congress enacted the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. 4801-4852. Section 1758 of ECRA (as codified under 50 U.S.C. 4817) authorizes the Bureau of Industry and Security (BIS) to establish appropriate controls on the export, reexport or transfer (in-country) of emerging and foundational technologies. Pursuant to ECRA, on November 19, 2018, BIS published an advance notice of proposed rulemaking (November 19 ANPRM) (83 FR

58201). That ANPRM identified Brain-Computer Interface (BCI) technology as part of a representative list of technology categories concerning which BIS, through an interagency process, sought public comment to determine whether there are specific emerging technologies that are essential to U.S. national security and for which effective controls can be implemented.

Comments to the November 19 ANPRM on Brain-Computer Interface Technology

In response to its November 19 ANPRM, BIS received approximately 13 comments related to the potential designation of BCI technology as an emerging technology. The substance of these comments is summarized in the following paragraphs.

One respondent noted that BCI technology, although still in the early stages of development, is currently available in Wassenaar Arrangement participating countries (including the United States), as well as in other countries.

Similarly, another respondent indicated that emerging BCI technology has important applications in human health care and assistive technologies and that, consequently, overly broad export controls on such technology could hinder research in these areas. In addition, a respondent in the aerospace sector stated that overly broad export controls would discourage information sharing and thereby hinder BCI research and development projects in the aerospace industry. This respondent also urged that license exceptions should apply to those situations involving technological collaboration with our allies.

Another respondent noted that the imposition of export controls on the representative general categories of technology (including BCI technology) identified in BIS's November 19 ANPRM would impact the fields of automotive development (e.g., autonomous driving and

automotive safety), artificial intelligence, advanced materials development, human-machine interfaces and robotics. This respondent expressed the concern that the imposition of overly strict export controls on such technology by the United States could drive future research and development programs to other technologically sophisticated countries in Europe, Asia and the Americas that would not impose unilateral export controls on such technology. As examples of the possible adverse effect of export controls on such technology, this respondent cited the impact that the tightening of export controls had on the U.S. commercial satellite sector and on LiDAR controlled under ECCN 6A001 or ECCN 6A008.j.2.

One respondent urged that U.S. export controls on BCI technology be addressed through the establishment of harmonized multilateral controls. Otherwise, the imposition of export controls on such technology by the United States could adversely impact future collaboration with our allies (e.g., foreign companies might become reluctant to utilize U.S.-origin BCI products or technology if they were subject to unilateral export controls). This respondent also recommended that the United States view its national security interests more narrowly, observing that the United States likely would lose credibility in multilateral export control forums if it tried to tie its national security and economic security interests too closely together. This respondent also asked whether these controls would be applied, across-the-board, to all countries or if they would vary depending upon the country of destination. In addition, the respondent inquired as to whether the *de minimis* provisions in the Export Administration Regulations (EAR) would apply. how often the United States would evaluate and update the scope of these emerging technology controls, and what additional measures (i.e., other than obtaining export or reexport licenses) U.S. companies and non-US entities would be expected to take in order to protect such technology.

Another respondent also warned about the potential harm to U.S. technological leadership and competitiveness if the United States were to impose broad unilateral controls on emerging technologies (including BCI technologies), instead of working with our allies to develop and implement multilateral controls. This respondent stressed that any export controls that are imposed on emerging technologies must apply only to those emerging technologies that are determined to be essential to U.S. national security (e.g., export controls on such technologies should address specific U.S. national security concerns, rather than trade policy issues). In addition, this respondent urged that emerging technologies should not be controlled unless they are exclusive to the United States and encompass only core technologies. This respondent also recommended that U.S. controls should focus primarily on technology required for "development," rather than technology for "production" or "use." This respondent further urged that, to the extent possible, any future EAR controls on emerging technologies should be designed to complement the existing controls on the Commerce Control List and the EAR definitions that apply to similar items, and not be described in vague terms (e.g., as capable for use with one or more specified items).

One respondent observed that the digital information field of BCI technology is quite mature and that, consequently, digital information technologies should remain unencumbered for the free exchange and cross-pollination of advancements across borders. In a similar vein, another respondent stated that, if export controls on quantum computing and BCI technologies were not properly crafted, these controls could damage U.S. competitiveness and undermine U.S. technological leadership by slowing development, limiting resources, reducing market participation and limiting collaborative opportunities. This respondent emphasized that, in developing and implementing export controls on such technologies, an effective partnership among government, industry and academia would be essential.

Process to Identify and Control Emerging Technology

Under ECRA, emerging and foundational technologies are those essential to the national security of the United States, but not described in Section 721(a)(6)(A)(i)-(v) of the Defense Production Act of 1950 (50 U.S.C. 4565(a)), as amended. Section 1758(a) of ECRA (50 U.S.C. 4817(a)) outlines an interagency process for identifying emerging and foundational technologies. This process considers both public and classified information, as well as information from the Emerging Technology Technical Advisory Committee and the Committee on Foreign Investment in the United States. In identifying specific emerging technologies, this process also takes into account all of the following:

- The development of the emerging technologies in foreign countries;
- The effect export controls might have on the development of the emerging technologies in the United States; and
- The effectiveness of export controls on limiting the proliferation of the emerging technologies in foreign countries.

In addition, Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)) requires that the interagency process for identifying emerging technologies include a notice and comment period.

The Secretary of Commerce must establish appropriate controls on the export, reexport or transfer (in-country) of technology identified pursuant to the Section 1758 process. In so doing, the Secretary must consider the potential end-uses and end-users of emerging and foundational technologies, and the countries to which exports from the United States are restricted (e.g., embargoed countries). While the Secretary has discretion to set the level of export controls, at a minimum a license must be required for the export of such technologies to countries subject to a U.S. embargo, including those countries subject to an arms embargo.

BCI technology has been identified as a technology for evaluation as a potential emerging technology, consistent with the interagency process described in Section 1758 of ECRA. Consequently, BIS is publishing this ANPRM to obtain feedback from the public and U.S. industry concerning whether such technology could provide the United States, or any of its adversaries, with a qualitative military or intelligence advantage.

Fundamentally, BCIs provide a direct communication pathway between an enhanced or wired brain and an external device, with bidirectional information flow. BCIs frequently involve a process in which brain signals are acquired, analyzed and then translated into commands that are: (1) used to control machines; (2) potentially transferred to other humans; or (3) used for human assessment or enhancement. Medical uses of BCI technology include replacing or restoring useful function to people disabled by neuromuscular disorders such as amyotrophic lateral sclerosis, cerebral palsy, stroke, or spinal cord injury.

BCI technology can also be a promising interaction tool for the public, with many potential applications in multimedia, entertainment and other fields. This technology will also have potential for military use in enhancing the capabilities of human soldiers, including collaboration for improved decision making, assisted-human operations, and advanced manned and unmanned military operations.²

Although the ability to apply BCI technology remains subject to certain limitations (e.g., approximately 15–30% of individuals currently are thought to be unable to produce brain signals

¹ Krucoff, M. O., Rahimpour, S., Slutzky, M. W., Edgerton, V. R., Turner, D. A. (2016), "Enhancing Nervous System Recovery through Neurobiologics, Neural Interface Training, and Neurorehabilitation," Neuroprosthetics, 10 (584).

² Binnendijk, A., Marler, T., Bartels, E. M. (2019), "Brain-Computer Interfaces: U.S. Tactical Military Applications and Implications," RAND Report RR-2996-CGRS.

robust enough to operate a BCI), the scientific community is addressing these limitations through strategies such as: (1) an adaptive machine learning approach that incorporates neurophysiological and psychological traits; and (2) the development of more advanced sensors (e.g., a coordinated network of independent, wireless microscale neural sensors that are able to gather data from much larger groups of brain cells than most current BCI systems).

Request for Comments

Consistent with Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), this ANPRM provides the public with notice and the opportunity to comment for the purpose of evaluating BCI technology as an emerging technology. Consequently, BIS welcomes comments on this ANPRM that would address, but not necessarily be limited to, the following questions. If specific BCI systems are discussed as part of any response to these questions, the public is requested to address the effectiveness of such systems (e.g., with respect to validation, assessment, detection of errors and ability to operate, as intended, for all types of individuals).

- (1) What specific uniform standards for BCI technology would need to be adopted to ensure their application on a global basis (i.e., as international standards for BCI technology)?
- (2) Where does the development of BCI in the United States stand with respect to other countries (e.g., is the United States on the forefront of BCI technology development)?
- (3) Is BCI technology currently available for commercial use in certain foreign countries and, if so, where and for what specific purposes (e.g., have foreign companies already developed devices or chips for specific commercial applications)?
- (4) Has the current stage of development with respect to invasive and/or non-invasive BCI technology reached the point at which such technology is ready for commercial production and use?
 - (5) Is the main progress with respect to non-invasive brain signal sensors being made in

terms of real-time algorithms designed to transform neural signals into commands (i.e., what is developing faster: "software" (algorithms) or hardware (sensors))?

- (6) What impact would the establishment of export controls on BCI technology have on U.S. technological leadership (i.e., not only in the field of BCI technology, but overall) and would this impact be distinctly different if controls were placed primarily on "software" as opposed to hardware, or *vice versa*?
- (7) How is the future development of artificial intelligence (AI) technology or other emerging technologies likely to impact the development of BCI technology, or *vice versa*?
- (8) What types of ethical or policy issues are likely to arise from the use of BCI technology (e.g., for medical or military purposes)?
- (9) What kinds of risks and benefits currently exist, or are likely to arise, as a result of the application of BCI technology?
- (10) What are the potential advantages or disadvantages of using invasive and non-invasive BCI chips/sensors and related "software" (e.g., algorithms for signal processing) for specific applications? To what extent would these advantages or disadvantages correspond (or differ) based upon whether invasive or non-invasive BCI chips/sensors and related "software" were being used?
- (11) Are there any BCI technologies that are significantly more vulnerable than others to cybersecurity threats (e.g., military systems employing BCI technologies that could adversely impact U.S. biodefense)?
- (12) What is the potential for transmitted BCI data to be hacked or manipulated to influence the user or machine? Is such data inherently more vulnerable to hacking or manipulation than other forms of data? Would the invasive or non-invasive characteristics of BCI data have any impact on the potential vulnerability of such data?

technology as an emerging technology, BIS encourages comments that would help it to determine:

- (1) Which aspects of BCI technology would be more likely to require monitoring by the U.S. Government (USG); and
- (2) Whether specific USG policies and regulations, as well as industry standards, need to be established before this technology becomes widely available for use in commercial applications.

BIS also welcomes comments concerning whether export controls on BCI technology should be implemented multilaterally (rather than unilaterally), in the interest of increasing their effectiveness and minimizing their impact on U.S. industry. As noted above, a number of respondents who commented on BIS's November 19 ANPRM indicated their preference for multilateral export controls over unilateral export controls, because the former typically place U.S. industry on a more level playing field versus producers/suppliers in other countries. In this regard, note that Section 1758(c) of ECRA (as codified under 50 U.S.C. 4817(c)) provides that "the Secretary of State, in consultation with the Secretary [of Commerce] and the Secretary of Defense, and the heads of other Federal agencies, as appropriate, shall propose that any technology identified pursuant to subsection (a) [of ECRA] be added to the list of technologies controlled by the relevant multilateral export control regimes." Subsection (a) of section 1758 (as codified under 50 U.S.C. 4817(a)) addresses the interagency process for identifying emerging technologies.

BIS also encourages comments that address issues raised in the November 19 emerging technology ANPRM public comments (as summarized above) and any other BCI technology topics that they consider to be relevant to this inquiry. The information provided by the respondents in response to this ANPRM will assist BIS in evaluating BCI as a potential

emerging technology for the purpose of formulating export control policies that will be both

effective and appropriate, with respect to their objective and scope.

Comments should be submitted to BIS as described in the ADDRESSES section of this

ANPRM and must be received by BIS no later than [INSERT DATE 45 DAYS AFTER DATE

OF PUBLICATION IN THE FEDERAL REGISTER].

This rule has been designated a "significant regulatory action," although not

economically significant, under Executive Order 12866. Accordingly, this rule has been

reviewed by the Office of Management and Budget (OMB).

Matthew S. Borman,

Deputy Assistant Secretary

for Export Administration.

[FR Doc. 2021-23256 Filed: 10/25/2021 8:45 am; Publication Date: 10/26/2021]